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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Drug Evaluation and Research (CDER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CDER's public advisory committees. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by [*insert date 30 days after date of publication in the* **Federal Register**] for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by [*insert 30 days after date of publication in the* **Federal Register**].

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ADDRESSES: All letters of interest and nominations should be submitted in writing to Igor Cerny (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Igor Cerny, Advisors and Consultants Staff (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001.

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act of 1997 (FDAMA) (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the drug manufacturing industries. Although not required for existing committees, to keep within the spirit of FDAMA, the agency intends to add nonvoting industry representatives to all CDER advisory committees identified in the following paragraphs.

I. CDER Advisory Committees

1. Advisory Committee for Pharmaceutical Science

Advises on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

2. Advisory Committee for Reproductive Health Drugs

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in obstetrics, gynecology, and contraception.

3. Anesthetic and Life Support Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.

4. Anti-Infective Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

5. Anti-Viral Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), HIV-related illnesses, and other viral, fungal, and mycobacterial infections.

6. Arthritis Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases.

7. Cardiovascular and Renal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational and human drug products for use in the treatment of cardiovascular and renal disorders.

8. Dermatologic and Ophthalmic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human of dermatologic and ophthalmic disorders.

9. Drug Safety and Risk Management Advisory Committee (formerly Drug Abuse Advisory Committee)

Advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health

and Human Services and the Department of Justice with the regard to safety, efficacy, and abuse potential, risk management, risk communication and quantitative evaluation of spontaneous reports, and recommends actions to be taken by the Food and Drug Administration with regard to marketing, investigation and control of such drugs or other substances.

10. Endocrinologic and Metabolic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

11. Gastrointestinal Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal disorders.

12. Nonprescription Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of the over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

13. Oncologic Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for the use in the treatment of cancer.

14. Peripheral and Central Nervous System Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic disease.

15. Psychopharmacologic Drug Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and related fields.

16. Pulmonary-Allergy Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

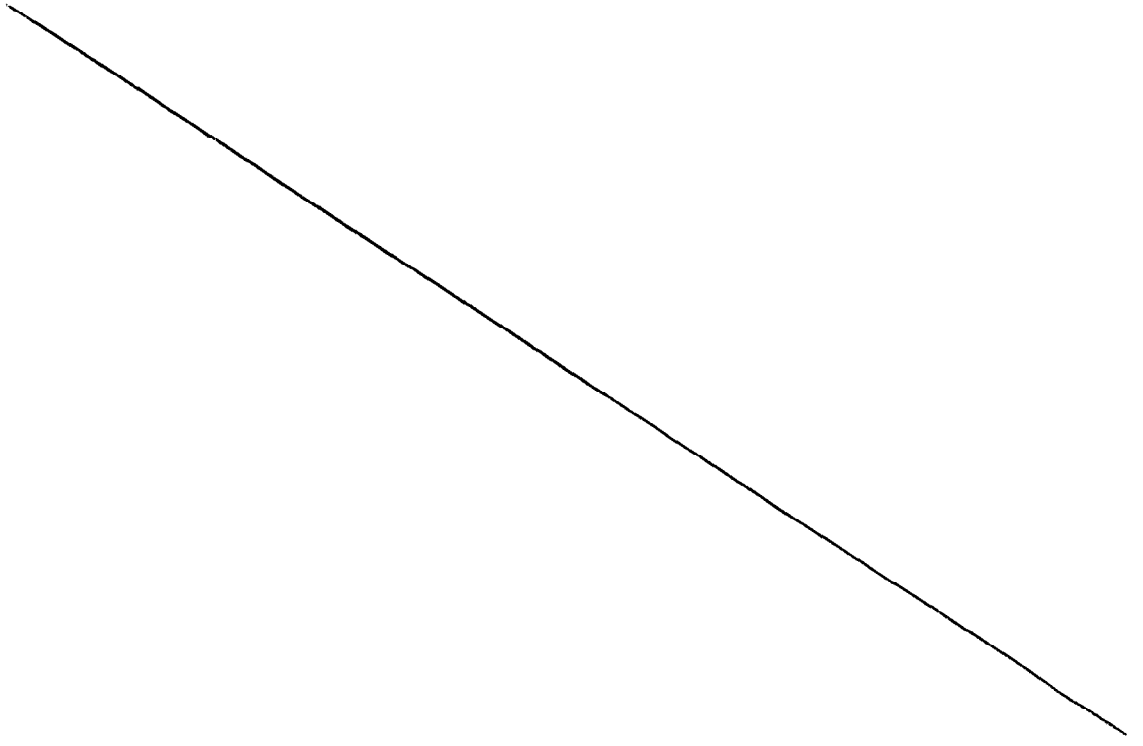
II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document. Within the subsequent 15 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for that committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from drug manufacturing industry.



This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app 2) and 21 CFR part 14, relating to advisory committees.

BBodo 6-2-03 RES

Dated: 5/29/03

May 29, 2003.

Peter J. Pitts,
Associate Commissioner for External Relations.

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